

Gerald Bohm  
Senior Counsel



April 8, 1997

Robert J. Moore  
Center for Food Safety and Applied Nutrition (HFS-456)  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204

RE: Docket No. 96N-0417

Dear Mr. Moore:

*I write to you on behalf of Roche Vitamins Inc. to request a ninety (90) day extension of proposed rules published by FDA on February 6, 1997 entitled Current Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Supplements.*

*An extension of the comment period is critical to our company as well as the industry. The requirement for comment on these proposals by May 7, 1996 will not provide sufficient time to fully understand the proposed rules, to fully determine the potential applicability and/or impact of HACCP and to comment on the changes as appropriate. Many of the issues covered under these regulations have been raised for the first time and are subject to many interpretations.*

*We hope the FDA will look favorable upon this request.*

Sincerely,

  
Gerald Bohm

cc: Dockets Management Branch (6 copies)  
Fred Shank, Ph.D.  
Elizabeth Yetley, Ph.D.  
Frank Girardi  
Barbara Kowal

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